



DEPARTMENT OF HEALTH AND HUMAN SERVICE

4FI-35  
Public Health Service *m2320n*

Food and Drug Administration  
New Orleans District  
Southeast Region  
4298 Elysian Fields Ave.  
New Orleans, LA 70122

Telephone: 504-589-6341  
FAX: 504-589-6360

January 21, 1999

**WARNING LETTER NO. 99-NOL-12**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Dr. Mary Maitland DeLand, President  
DeLand & Noell Corp.  
d.b.a. Romagosa Radiation Oncology Center  
917 General Mouton Avenue  
Lafayette, Louisiana 70501-8511

Dear Dr. DeLand:

During an inspection of your contract blood and blood component irradiation facility, located at 917 General Mouton Avenue, Lafayette, Louisiana, on December 3, 4, & 7, 1998, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (CFR), Part 606.

Deviations noted included: 1) failure to validate the number of units which may be stacked and still comply with the depth requirements specified by the manufacturer; 2) failure to verify through measurement that products do not exceed the manufacturer's specification for depth for each run of the linear accelerator; 3) incomplete written procedures for the irradiation of blood and blood products in that the number or configuration of blood products which may be irradiated at one time is not specified; and, 4) written procedures are not consistent with memorandum of understanding with your customers in that the number of monitor units to be delivered differs.

Although your written response of December 15, 1998, addressed some of our concerns, several of the deficiencies listed on the FDA-483 were not adequately corrected. These include: 1) lack of instruction for the placement or arrangement of the blood products and the maximum number that may be irradiated at one time; 2) failure to address validation procedure for units that are stacked or overlapped showing equivalence to manufacturer's specifications or your written procedures; and, 3) failure to document that the 1.5 cm thickness specification for a field size of 10 cm x 10 cm holds true for the 32 cm x 32 cm field size of the [REDACTED] linear accelerators.

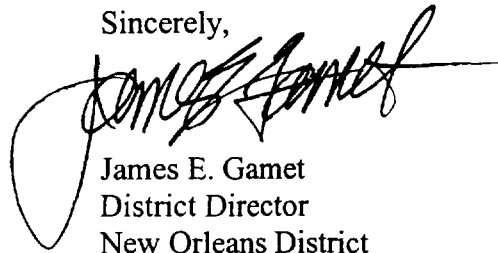
The above violations are not intended to be an all-inclusive list of deficiencies at your facilities. As the President, it is your responsibility to assure that all of your establishments are in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Olsen at telephone number (504) 589-7166.

Sincerely,

A handwritten signature in black ink, appearing to read 'James E. Gamet', with a large, sweeping flourish extending from the bottom left.

James E. Gamet  
District Director  
New Orleans District

Enclosure: FDA-483

cc: Mr. Grover R. Bass, Chief Radiation Therapist  
Deland & Noell Corporation  
917 General Mouton Ave.  
Lafayette, Louisiana 70501-8511